



# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/085,418 02/28/2002		Alexandra Louise Lowe	50223/USTN2/UST	4860	
22847 7	590 09/23/2004		EXAMINER		
	BIOTECHNOLOGY,	KATCHEVES, KONSTANTINA T			
PATENT DEP. 3054 CORNW.		ART UNIT	PAPER NUMBER		
P.O. BOX 1223	57	1636			
RESEARCH T	RIANGLE PARK, NC	DATE MAILED: 09/23/2004			

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	n No	Applicant(s)				
Office Action Summary		Application	III 140.					
		10/085,41	8	LOWE ET AL.				
		Examiner		Art Unit				
			a Katcheves	1636				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1)🖂	Responsive to communication(s) fil	led on <u>28 February 20</u> 0	<u>)2</u> .					
'=	This action is <b>FINAL</b> .	2b)⊠ This action is n						
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	ion of Claims							
5)□ 6)⊠ 7)□ 8)□ Applicat 9)□	Claim(s) 1-12 is/are pending in the 4a) Of the above claim(s) is/a Claim(s) is/are allowed.  Claim(s) 1-12 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restrict to the specification is objected to by the drawing(s) filed on is/are  Applicant may not request that any objected to applicant may not request that any objected to some series are subjected to by the drawing(s) filed on is/are	are withdrawn from co iction and/or election r he Examiner. e: a)  accepted or b)	equirement. ☐ objected to by the					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority (	under 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No. 09/423,143.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
2) Notice 3) Infor	nt(s)  ce of References Cited (PTO-892)  ce of Draftsperson's Patent Drawing Review  mation Disclosure Statement(s) (PTO-1449 or  er No(s)/Mail Date 1/15/04.		4) Interview Summan Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	)ate	O-152)			

### **DETAILED ACTION**

Claims 1-12 are pending in the present application.

### Claim Objections

Claim 11 is objected to because of the following informalities: Claim 11 appears to be missing a verb between the subject, vector, and predicate," two tandem copies". Appropriate correction is required.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bedbrook et al. (WO 97/01952).

The invention of the instant claims is broadly drawn to a vector for enhancing the inhibition of a selected target gene comprising a gene silencing vector having an inverted repeat. In a more specific embodiment, the vector comprises a promoter region, a 5' untranslated region, a DNA sequence and a 3' untranslated region containing a polyadenlyation signal. The inverted repeat of the vector may be in the 5' untranslated region of the construct.

Application/Control Number: 10/085,418

Art Unit: 1636

Bedbrook et al. disclose a vector for inhibiting the expression of a target gene, ACC synthase, within an organism, tomato plant. See page 5, lines 5-17. The construct of Bedbrook et al. comprises a promoter region, p35S, a 5' untranslated region, leader sequence of the Cab22R gene, a transcribed DNA sequence, a fragment of ACC synthase, and a 3' untranslated region, nos3. See Figure 4 and page 5, lines 24-33. The vector of Bedbrook et al. comprises three copies of the construct arranged as inverted repeats. See page 6, lines 2-4. Three copies of the construct would encompass three copies of the 5' untranslated region. The construct also includes a LacA polylinker sequence used as a spacer for cloning purposes. See page 5, line 29 and page 10, linese 17-18. Bedbrook et al. also disclose a usue for their vector in a method for controlling the expression of Acc synthase in tomato plants by insertion of said vector into the genome of the plant. See abstract.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1636

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorer et al. (Cell Vol.77 pp993-1002 1994).

The invention of the instant claims is relied upon as described above.

Dorer et al. Teach a vector for inhibition of a target gene, mini-white, comprising P transposon end, a β-galactosidase gene, plasmid sequences and the mini-white gene including the 5' and 3' untranslated regions. See Figure 1. dorer et al. Show that when this vector is integrated into the genome of a transgenic Drosophila as an inverted repeat the expression of the endogenous mini-white gene is silenced. See Figure 3. One of ordinary skilled in the art would have been motivated to make and use a modified vector of Figure 1 which includes the inverted repeats of Figure 3 for gene silencing because Dorer et al. teach that inverted duplication lead to overall repression of the mini-white gene. See page 999, first column, third paragraph. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Application/Control Number: 10/085,418

Art Unit: 1636

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a vector in the preamble while claim 5 which depends from claim is drawn to a method in the preamble. Based on this inconsistency, it is unclear in these two claims whether Applicant is claiming a product or a method.

Claim 6 recites the term "enhanced." It is unclear whether the vector itself or the function of the vector, gene silencing, is enhanced.

Claim 9 recites the term "selected fragments." There is insufficient antecedent basis for this phrase in the claim.

### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/085,418

Art Unit: 1636

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves Examiner Art Unit 1636

PRIMARY EXAMINER